Proprietary

SPECIALTY GUIDELINE MANAGEMENT

FUSILEV (levoleucovorin) powder/solution KHAPZORY (levoleucovorin) powder levoleucovorin solution

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- 1. Levoleucovorin/Fusilev/Khapzory is indicated for rescue after high-dose methotrexate therapy in osteosarcoma.
- 2. Levoleucovorin/Fusilev/Khapzory is indicated for diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination.
- 3. Levoleucovorin/Fusilev/Khapzory is indicated for use in combination chemotherapy with fluorouracil for treatment of metastatic colorectal cancer.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 3 months may be granted for any of the settings listed below when leucovorin is not an appropriate/available option at this time:

- A. Rescue treatment after high-dose methotrexate therapy
- B. Treatment of a folate antagonist overdose
- C. Combination therapy with fluorouracil based chemotherapy regimens

III. REFERENCES

- 1. Fusilev [package insert]. East Windsor, NJ: Acrotech Biopharma LLC.; November 2020.
- 2. Levoleucovorin injection [package insert]. Princeton, NJ: Sandoz Inc.; December 2020.
- 3. Khapzory [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; March 2020.
- The NCCN Drugs & Biologics Compendium[®] © 2021 National Comprehensive Cancer Network, Inc. Available at: <u>https://www.nccn.org</u>. Accessed March 1, 2021.

levoleucovorin-Fusilev-Khapzory 1661-A SGM P2021.docx

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